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10/684,904	10/14/2003	Peter M. Bonutti	780-A03-012B	3567

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FGGBB-MARCTEC
21355 EAST DIXIE HIGHWAY
SUITE 115
MIAMI, FL 33180

EXAMINER	
HOFFMAN, MARY C	

ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/684,904	**Applicant(s)** BONUTTI, PETER M.
	Examiner MARY HOFFMAN	**Art Unit** 3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-16,18-28,30-33,35-38,40-46 and 51-72* is/are pending in the application.

4a) Of the above claim(s) *63-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-16,18-28,30-33,35-38,40-46,51-62 and 68-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date *06/03/2010,06/03/2010,06/03/2010,06/03/2010*.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's argument in the reply filed on 06/03/2010 is acknowledged. The traversal is on the ground(s) that claims 63-67 should not be restricted because Applicant believes the claims do not present further search burden. This is not found persuasive because claims 63-67 recite separate method steps which will require a further search. It is noted that Applicant may still make narrowing amendments by including independent method claims that recite the same method steps as the currently pending claims plus any additional narrowing limitations or by adding dependent method claims.

The requirement is still deemed proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 4-16, 18-19, 24-25, 28-33, 35-38, 40-46, 51-52, 57-61 and 68-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haines et al. (U.S. Patent No. 5,643,272) in view of Waddell (U.S. Patent No 6,174,314). Also see evidentiary patent to Caspari, Patent No. 5,395,376.

Haines et al. disclose a method of performing surgery on a leg of a patient, comprising making an incision in a knee portion of the leg; displacing a patella in the knee portion of the leg from a normal position to an offset position (see FIG. 11); and positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg and cutting bone of the leg while the patella is maintained offset from a normal position. The method further comprising cutting an end surface of at least one of the upper or lower portions of the leg. The method further comprising moving at least one implant through the incision while the patella is offset from the normal position; and connecting the at least one implant with the cut end portion of at least one of the upper or lower portions of the leg. The method further comprising connecting a guide member to at least one of the upper or lower portions of the leg (FIG 11). The guide member is connected to the upper portion of the leg, the upper portion being a femur, the guide member including a first end portion in engagement with a lateral condyle of the femur, the first end portion offset medially from a lateral edge portion of the lateral condyle, and a second end portion in engagement with a medial condyle of the femur, the second end portion offset laterally from a medial edge portion of the medial condyle. The method further comprising moving a guide member into the incision, the guide member including opposite ends spaced apart by a distance which is less than a distance between a lateral epicondyle and a medial epicondyle on a femur; positioning the guide member on the femur in the leg of the patient with the opposite ends of the guide member aligned with an axis through the lateral and medial epicondyles; positioning the cutting tool on the guide member; and moving the cutting tool along a guide surface on the guide member to cut the lateral and medial epicondyles on the femur. The method comprising cutting the lateral and medial condyle of the femur. The method further comprising cutting an end surface of the tibia. The method further comprising moving at least one tibial implant through the incision while the patella is offset from the normal position; and connecting the at least one tibial implant with the cut end portion of the tibia. Haines et al. further disclose a method of performing surgery on a leg of a patient, comprising making an incision in a knee portion of the leg; displacing a patella in the knee portion of the leg from a normal position to an offset position; and positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg; and supporting the patient with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position. The method further comprising initiating a cut with the cutting tool along an end portion of at least one of the upper or lower portions of the leg to define a cutting surface; and completing the cut while guiding the cutting tool along the cutting surface formed during making of the initial cut in an end portion of at least one of the upper or lower portions of the leg. Haines et al. further disclose a method of performing surgery on a leg of a patient, comprising making an incision in a knee portion of the leg; displacing a patella in the knee portion of the leg from a normal position to an offset position; positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg; exposing a first portion of the upper portion of the leg through the incision; effecting relative movement between the upper and lower portions of the leg; and exposing a second portion of the upper portion of the leg through the incision. Making the incision in the knee portion of the leg comprises making the incision adjacent to a medial edge portion of the patella. Making the incision in the knee portion of the leg comprises making an incision having a length between about seven and thirteen centimeters. Haines et al. further disclose a method of performing surgery on a leg of a patient, comprising: making an incision in a knee portion of the leg; displacing a patella in the knee portion of the leg from a normal position to an offset position; positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg; and wherein displacing the patella from the normal position to the offset position comprises moving the patella laterally relative to the knee portion of the leg. Haines et al. further disclose a method of performing a knee arthroplasty surgery on a leg of a patient, comprising making an incision in a knee portion of the leg of the patient; cutting an inner side portion of a patella in the knee portion of the leg, the patella being disposed in a normal position relative to the knee portion of the leg; and displacing the patella from the normal position to an offset position. The method further comprising the steps of: sequentially passing portions of an implant through said incision; and, affixing at least two of said implant portions, one to the other, within the leg, in association with one side of the knee joint. The method further comprising the steps of: replacing at least a portion of a single condyle with an implant; and, replacing at least a portion of a trochlear groove with an implant. The cutting tool is fabricated at a lower cost than a reusable cutting tool by being designed to be used in a single procedure and thereafter discarded (product-by-process recitation).The method further comprising the step of: positioning said cutting tool proximal to a side surface of the distal end of the femur to guide cutting the bone of the leg.

Haines et al. does not explicitly state whether the patella is everted (i.e. with the inner side of the patella facing inward), and does not disclose positioning a guide assembly proximally to the patella, the guide assembly including a pair of substantially parallel arms and a slot having a guide surface configured for receiving a patella cutting tool, and inserting a patella implant, and the order of the steps is not specifically disclosed, and making an incision having a length between about seven and thirteen centimeters, i.e. not more than 13 centimeters. However, it is noted that a broad reading of the Haines reference will suggest to a person of ordinary skill in the art that the patella should not be everted, for example, the cutting guides are constructed to be used from a lateral or medial approach to avoid interference with the patella.

Further, Waddell discloses that the patella should not be everted and should remain facing inward during the cutting and positioning steps, including resection of the patella (column 8, lines 14-15) in order to decrease the failure of total knee arthroplasty (col. 2, lines 63-67 and col. 3, lines 1-8), and Waddell teaches an improved patella guide assembly and method, including positioning a guide assembly proximally to the patella, the guide assembly including a pair of substantially parallel arms and a slot having a guide surface configured for receiving a patella cutting tool, to achieve accurate placement and functioning of the resection patella (Abstract). Waddell also discloses a patella implant as part of knee arthroplasty

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Haines et al. including not everting the patella and including placing a guide assembly proximal the patella and inserting a patella implant in view of Waddell to decrease the chance of failure of the surgery and to achieve accurate placement and functioning of the resection patella. It would have further been obvious to perform the steps in various orders according to common sense, as long as the different order does not affect the overall method.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to perform the method of Haines et al .in view of Waddell making the incision in the knee portion of the leg comprises making an incision having a length between about seven and thirteen centimeters (i.e. not more than 13 centimeters), since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. Moreover, the desirability of minimally invasive incisions, i.e. smaller incisions, was well known in the surgical arts, since smaller incisions correspond to lower risks of complications such as infection. Applicant is referred to Caspari, evidentiary Patent No. 5,395,376, which recommends a reduced size incision (ref. #280) of one to one-half inch, showing that it was known in the prior art that reduced sized incisions were desirable.

Regarding claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haines et al. (U.S. Patent No. 5,643,272) in view of Waddell (U.S. Patent No 6,174,314) further in view of Whitt (U.S. Patent No. 4,373,709)

Haines et al. in view of Waddell further disclose a method of performing surgery on a leg of a patient, comprising making an incision in a knee portion of the leg; displacing a patella in the knee portion of the leg from a normal position to an offset position; and positioning a cutting tool proximal to at least one of an upper or a lower portion of the leg. Haines et al. in view of Waddell does not disclose supporting the patient with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position.

Whitt discloses a surgical limb holder that allows the surgeon to adjust the position of the knee during a surgical procedure. Fig. 1 of Whitt shows the lower portion of the leg suspended from the upper portion of the leg during the surgery. This device allows a great variety of sizes, positions, and attitudes so that the limb can be held in any position which will enhance and facilitate the surgery (col. 1. lines 19-21) and thus contemplates that a surgery may be performed with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position, if such position is determined by the surgeon to facilitate the surgery.

Therefore, it would have been obvious to perform the method of Haines et al. in view of Waddell with supporting the patient with the lower portion of the leg suspended from the upper portion of the leg, wherein the lower portion remains suspended from the upper portion while the incision is made in the knee portion of the leg and the patella is moved to the offset position further in view of Whitt, since Whitt shows that the lower leg can be suspended during a surgery to facilitate and enhance the surgery.

Regarding claim 57, Haines et al. in view of Waddell further discloses the claimed invention except for the implant including a plurality of layers, at least one of said layers including at least one material selected from the group consisting of: fetal cells, bone cells, embryonal cells, stem cells. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the implant of Haines et al. in view of Waddell out of fetal cells, bone cells, embryonal cells, stem cells, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Claims 22-23, 54-56, 62 and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haines et al. (U.S. Patent No. 5,683,469) in view of Waddell (U.S. Patent No 6,174,314) further in view of Wang et al. (U.S. Patent No. 6,102,850).

Haines et al. in view of Waddell discloses the claimed invention except for using an endoscope and robotics.

Wang et al. discloses using an endoscope and robotics to assist the surgeon (see Abstract)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Haines et al. in view of Waddell to use endoscope and robotics in view of Wang et al. to assist the surgeon.

Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haines et al. (U.S. Patent No. 5,683,469) in view of Waddell (U.S. Patent No 6,174,314) further in view of Gustilo (U.S. 5,733,292).

Haines et al. in view of Waddell discloses the claimed invention except for using transducers.

Gustilo et al. disclose using transducers to provide information on forces within the joint.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Haines et al. in view of Waddell to use transducers in view of Gustilo et al. to provide information on forces within the joint.

Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Haines et al. (U.S. Patent No. 5,683,469) in view of Waddell (U.S. Patent No 6,174,314) further in view of Whitt (U.S. Patent No. 4,373,709).

Haines et al. in view of Waddell discloses the claimed invention except for a supporting member including actuating and controlling means, operative to move the lower portion of the leg.

Whitt discloses using a supporting member including actuating and controlling means, operative to move the lower portion of the leg to hold the leg in the optimum position during surgery.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to perform the method of Haines et al. in view of Waddell using a supporting member including actuating and controlling means, operative to move the lower portion of the leg in view of Whitt to hold the leg in the optimum position during surgery.

Response to Arguments

Applicant's arguments filed 06/03/2010 have been fully considered but they are not persuasive.

Applicant argues that Haines in view of Waddell does not show the claim method steps, in particular, that the patella is not everted. The examiner respectfully disagrees. It is noted that a broad reading of the Haines reference will suggest to a person of ordinary skill in the art that the patella should not be everted, for example, the cutting guides are constructed to be used from a lateral or medial approach to avoid interference with the patella. Moreover, Waddell suggests the benefits of keeping the patella in an anatomical position during cutting and positioning.

Therefore, the rejection is deemed proper and maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733